Evidence Based Clinical Guidelines for the Use of the Pneumatic Post-Amputation Mobility Aid (PPAM Aid) in Persons with Lower Limb Amputations

About this document:

This document described the evidence based clinical recommendations for best physiotherapy practice of the Use of the Pneumatic Post Amputation Mobility aid of persons with lower limb amputation as described by the literature and expert opinion.

This guideline will update:

(2008.) *Clinical Guidelines for the Use of the PPAM Aid.* 1st Edition. Scottish Physiotherapy Amputee Research Group: Glasgow. (Paper format only and at a cost of £10)

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Acknowledgements:

Nominal Group Technique Panel
Delphi Participants
British Association for Chartered Physiotherapist in Limb Absence Rehabilitation (BACPAR)
Scottish Physiotherapy Amputee Research Group (SPARG)

These clinical guidelines present the best available evidence. Healthcare professionals are expected to take it into account when exercising their clinical judgement. However, these clinical guidelines do not override the responsibility of healthcare professional to make appropriate decisions in consideration to and consultation with the patient and/or their carer.

Evidence Based Clinical Guidelines for the Use of the Pneumatic Post-Amputation Mobility Aid (PPAM Aid) in Persons with Lower Limb Amputations

Aims of the Guidelines

This guideline aims to:

- Facilitate best practice for physiotherapists and other clinicians using of the PPAM aid in lower limb amputation rehabilitation
- Identify evidence and to establish expert opinion so that recommendations can be made
- Promote a quality and consistent physiotherapy management that is standardized across NHS services and private practices
- Inform professionals, including other members of the multidisciplinary team, involved with using the PPAM aid

Objective of the Guidelines

This guideline has been developed to:

- Appraise the current literature and collate physiotherapist's knowledge to make recommendations for best practice for the use of the PPAM aid in management of persons with lower limb amputation
- Disseminate information
- Identify gaps in the evidences and areas for further research

Methods

Scope of the Guidelines

These guidelines include details relating specifically to the use of the PPAM aid as an intervention in the rehabilitation of persons following lower limb amputation. They are intended to be a framework to inform best practices that all clinicians should aim to achieve as part of their professional responsibilities.

These guidelines address the prescription of PPAM aid with major levels of lower limb amputation, including bilateral amputation, for all underlying aetiologies. The levels of amputation covered by this guideline are transfemoral, knee disarticulation, and transtibial.

These guidelines commence when the patient is assessed for suitability for the use of the PPAM aid and conclude upon delivery of prosthesis. These guidelines do not cover interventions other than the PPAM aid, other care provided by members of the multidisciplinary team, or the management of upper limb amputees. The physiotherapy management beyond the use of the PPAM aid is addressed in the "*Evidence based clinical guidelines for the physiotherapy management of adults with lower limb protheses"*[1] and *"Clinical guidelines for the pre and post-operative physiotherapy management of adults with lower limb amputations".* [6]

The clinical question

The clinical question is unchanged from the previous edition of these guidelines:

Evidence Based Clinical Guidelines for the Use of the Pneumatic Post-Amputation Mobility Aid (PPAM Aid) in Persons with Lower Limb Amputations

What is the best practice for the use of the PPAM aid in the rehabilitation of persons with lower limb amputation?

The guidelines sought to determine if new evidence or clinical developments have changed what is considered to be best practice.

The literature search

The aim of the search was to review all existing, relevant literature regarding PPAM aid use. The literature search was defined by:

Inclusion Criteria

Manuscripts were included if they were:

- Relevant to lower limb amputation/amputees
- Relevant to adults (18 years of age or older)
- Relevant to all pathologies/aetiologies
- Relevant to use of PPAM aid as early walking aid
- Relevant to transfemoral, knee disarticulation, or transtibial
- Published after 1970
- English language
- Full text available

Exclusion Criteria

Manuscripts were excluded if they were related to:

- All other early walking aids, e.g. Femurett, AMA

Literature searches were undertaken in February 2019 and November 2020 using key words detailed below:

"PPAM aid" OR **"Pneumatic post amputation mobility aid**"

An electronic literature search was executed using the following databases: MEDLINE (PubMed), The Cumulative Index to Nursing and Allied Health Literature (CINAHL), Allied and Contemporary Medicine Database (AMED), and ProQuest. Reference list from the identified studies, as well as a grey literature search, were also examined to expand the results.

Results of Literature Search & Selection of Relevant Articles

The database and grey literature search identified a total of 43 papers – 8 from AMED, 6 from CINAHL, 18 from ProQuest, 6 from PubMed, and 5 from Medline. The removal of duplicates left a total of 25 studies. All remaining articles were checked by title and then abstract; articles were excluded if the appraisers did not feel the study was relevant to the guidelines. From the

remaining studies: 10 were excluded by title and 4 were excluded by the abstract as they did not meet the inclusion criteria or were not relevant to the research question (see Figure 1).

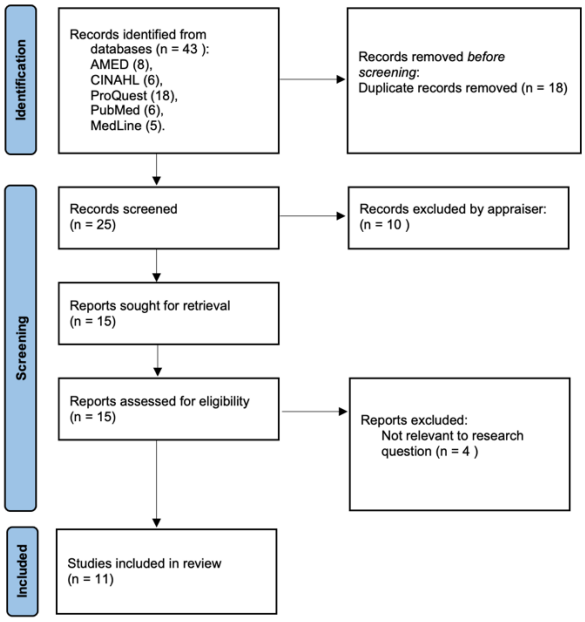

Figure 1: PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses)[2] flow diagram of studies retrieved from literature search. Adapted from Liberati et al. (2009).

The Appraisal Process

The selected studies were assessed and critiqued for content and quality using the Critical Appraisal Skills Programme (CASP)[3]. The use of CASP allows for the assessment of studies with research designs other than randomized controlled trials, and the standardized checklist appraises each study's methodology, population, risk of bias, and outcomes. Each study was appraised by two individuals.

The Consensus Process

The Nominal Group Technique (NGT) and Delphi Consensus Technique are group facilitation techniques that provide a method for collecting informed judgements from a group of experts on a specific issue when the literature does not supply sufficient evidence to develop recommendations.

The NGT was conducted as the first stage of the consensus process to generate statements that would be used Delphi Consensus. It consisted of a 2 hour long virtual meeting with discussion among 5 special physiotherapists from across 5 different NHS Scotland Health Boards. The group was asked two questions and submitted as many answers as they could generate through an electronic communal document. The responses were simplified and amalgamated through group discussion. The NGT developed 66 statements which would be used in a questionnaire to determine consensus. The questions asked in the NGT were:

- What are the main factors that influence your decision making when using the PPAM aid?

- What are the main factors that influence your management/rehabilitation decisions for PPAM aid progression?

The Delphi Consensus was an online questionnaire that was distributed through gatekeepers at the Scottish Physiotherapy Amputee Research Group (SPARG) and British Association of Chartered Physiotherapists in Limb Absence Rehabilitation (BACPAR). The questionnaires were completed anonymously, and participants were asked to answer whether they agree or disagree with the statements. If the statement reached 70% consensus of agreement, it was considered to be a recommendation that could be included in the guideline. The Delphi Consensus consisted of two rounds with any statements that did not meet the 70% agreement being amended based on comments by the participants. The first round had 46 of the 66 statements meeting the consensus threshold. In the second round, 9 of the remaining 20 statements reached consensus. Those that did not reach consensus were not amended or used in a third round on a decision by the research team.

Delphic Questionnaire Participants (n=86):

Years of Experience:
0 – 5 years – 1%
5 – 10 years – 12%
10 – 15 years – 20%
15 – 20 years – 21%
>20 years – 47%

NHS Band:
4: 1%
5: 1%
6: 26%
7: 56%
8 (a/b): 15%
Not designated: 1%

NHS Health Board & Trusts:
Greater Glasgow & Clyde NHS Scotland
Hertfordshire NHS Trust
Belfast Trust
NHS England North East
NHS England London
Liverpool University Hospital Foundation Trust
NHS England Gloucester
Sheffield Teaching Hospitals
NHS England South East
Barking, Havering & Redbridge NHS Trust

United Lincolnshire NHS Trust
Grampian NHS Scotland
NHS England Cornwall

NHS England North West
Ayrshire and Arran NHS Scotland
Lanarkshire NHS Scotland
New Zealand Artificial Limb Service
United Hospital Dorset
Guys and St Thomas NHS Foundation Trust
Swansea Bay University Health Board
Guernsey Health Service
Portsmouth Hospitals University Trust
Mid and South Essex Trust
NHS England Wessex
Countess of Chester
Betsi Cadwaladr
Tayside NHS Scotland
Northern Ireland
South Yorkshire
Manchester Foundation Trust
North Cumbria Integrated Care Trust
Nottingham University Hospitals
Western Sussex Hospital Trust
Imperial College Healthcare Trust
NHS England South East
Cardiff & Vale University Health Board
Livewell Southwest
NHS England West Midlands
University Hospitals of Derby and Burton NHS Foundation Trust
Lothian NHS Scotland
Private Practitioners

Guideline Development

The guideline was completed in 2023.

External Review and Stakeholder Feedback

SPARG Executive Committee
BACPAR Guideline Officers

Implementation & Dissemination

It is good practice that all guidelines be free to all who wish to access them as established by the Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities (http://oa.mpg.de/openaccess-berlin/belindeclaration).

SPARG and BACPAR will fund the publication and dissemination of the guidelines document and the poster will be distributed to members and physiotherapists upon request to improve accessibility of the information.

SPARG will support the promotion of the guidelines update at the local level with distribution to the ten vascular centres within Scotland. The guidelines were presented at the Annual Scientific Meeting of the Vascular Societies in November 2021, to disseminate to multidisciplinary audiences.

Dissemination of the guidelines can be furthered through the use of both SPARG and BACPAR social media networks and websites. In addition to these guidelines there are the manufacturers' online instructions with videos to demonstrate the application of the PPAM aid and user information produced by SPARG; all of which is available to download from the BACPAR website (http://bacpar.csp.org.uk/).

Audit

Comments on these guidelines should be sent to:
Fiona Davie-Smith
WestMARC, QEUH, G51 4TF

Any comments will be audited by the guideline development group. SPARG and BACPAR will also produce a questionnaire seeking feedback on the guidelines, which will influence content in later editions.

Review and Further Updates

SPARG will update these clinical guidelines every five years and continue to develop the evidence base to investigate best practice for PPAM aid.

Preface

This edition seeks to integrate new scientific evidence and current practice into recommendations.

The guidelines are divided into 6 sections for your ease of reference:

- Benefits of PPAM aid use
- Timing and Prescription of PPAM aid use
- Persons who can use the PPAM aid

- Precautions and things to monitor
- Applying the PPAM aid
- Progression of the PPAM aid

Each section includes relevant recommendations/ findings and a summary of the evidence; and suggestions for good practice. Throughout these sections, persons with lower limb amputation may be referred to as individuals, amputees, patients, or users.

In addition, the following supplementary document has been developed to support the guideline update:

- "Using the PPAM Aid" poster for use in the clinical environment that summarizes the key information from the guidelines and signposts to the full document for detailed recommendations for practice.

Introduction

The aim of rehabilitation post-amputation is to improve functional independence and return to activity. The rehabilitation process differs greatly among the Health Boards in the United Kingdom, and even more so between countries, but the process normally commences day one post-operatively in the hospital.[4] This includes transferring the patient up to sit in a wheelchair and transfer practice with some desensitization of the residual limb.[4] Rehabilitation encourage patients to engage in a programme of exercise including upper body strengthening, wheelchair mobility, and balance and coordination skills,[5] while maintaining the integrity of the residual limb.[6]

If able, the patient may progress to the use of an Early Walking Aid (EWA), which is a key component in relearning gait, postural reactions, and assessing potential to limb fitting. Several types of EWAs are available, varying from custom made temporary prostheses, to vacuum, or pneumatic devices. The pneumatic post-amputation mobility (PPAM) aid is the most used EWA following lower limb amputations.[7]

The PPAM aid consists of an inner and outer pneumatic cushion and sleeve enclosed by a frame. The larger out bag extends from the groin to below the residual limb, while the smaller inner bag cushions the distal end of the residuum. The PPAM aid has a simple rocker foot. It is available in three different lengths in both regular and bariatric sizes. A pump is supplied with the PPAM aid to inflate the pneumatic bags, which are equipped with quick-release valves to adjust pressures. Ortho Europe, the company that produces PPAM aids, provides the instructions to introduce the patient with an application at 20-30mmHg for 5 to 10 minutes, to increase the pressure and length of time until the patient is comfortable at 40 mmHg for 10 minutes before progressing to mobilization.[8]

Evidence Based Clinical Guidelines for the Use of the Pneumatic Post-Amputation Mobility Aid (PPAM Aid) in Persons with Lower Limb Amputations

Section I: Benefits of PPAM aid Use

Introduction:

The benefits of using an EWA following lower limb amputation are well documented in the literature. The main benefits are for the patient, but also extend to healthcare professionals and society.

Recommendations/Findings:

- Independent mobility with PPAM aid is a good predictor of successful limb fitting. (*Independent refers to a patient walking within parallel bars or using walking aids in a supervised rehabilitation environment)*
- PPAM aid can be used to improve cardiovascular fitness, strength, and exercise tolerance.
- PPAM aid can be used as an assessment tool for limb fitting.
- PPAM aid can help reduce hip and knee flexion contractures.
- PPAM aid can improve mood and give patients a boost with their rehabilitation.
- PPAM aid can be used for treatment and assessment.
- A joint goal, between physiotherapists and patients using the PPAM aid, of aiming to limb fit should be set.
- Patients who start PPAM aid use within 10 days have shorter time to casting and final discharge

Literature Evidence:

From the literature search, seven studies highlighted the potential advantages of using the PPAM aid. Barnett et al.[9] and Mazari et al.[10] both investigated the differences between the Amputee Mobility Aid (AMA) and the PPAM aid. Barnett et al.[9] examined different phases of the gait cycle, finding that the PPAM aid group of participants showed greater increases in prosthetic limb cadence, relative stance duration on the prosthetic limb, ankle plantarflexion during early stance and swing phase, and prosthetic limb hip range of motion, including a decrease in hip hitching demonstrating PPAM aid's advantages in gait training.

There was no difference between the groups for total rehabilitation time, time to prosthetic delivery, or the total number of treatments for the participants of Barnett's study,[9] but Mazari et al.[10] found the median number of treatments, the median duration of physiotherapy treatments, and time to prosthesis delivery was lower in the PPAM aid group. These finding echo the results of a retrospective analysis of transtibial persons with amputation by Lee et al.[11] which examined the relationship between PPAM aid use and rehabilitation milestones. Increased

frequency and early introduction of PPAM aid decreased the time to reach prosthetic casting, delivery, and physiotherapy discharge. These findings are imperative to highlight as in the

previous edition of the guidelines, it did not reach consensus that the use of the PPAM aid increased the likelihood of successful prosthetic outcome and patient independence. Further research needs to be done investigating the functional levels of prosthetic users, but it is confirmed that PPAM aid use has a relationship to rehabilitation outcomes.

Both Barnett et al. [9] and Mazari et al.[10] found no significant differences in walking velocities between PPAM aid and AMA, although initially Mazari et al.[10] found that PPAM aid had significantly faster 10-meter walk test. The rigid frame of PPAM aid made it easier and quicker to use, while those using the AMA had to navigate the control of knee. Despite the knee being held in extension with the PPAM aid, Mazari et al.[10] established there were no delays when transitioning to a prosthesis.

These studies identified that there is no clinical difference between the AMA and PPAM aid participants at discharge and although differences in gait adaptation during rehabilitation, there was not one EWA that was more beneficial for gait training. Mazari et al.[10] noted that the PPAM aid was significantly less expensive than the AMA, so the AMA should only be reserved for cases where the PPAM aid was unavailable to use. Redhead[12,13] and Cole[14] also highlighted the cost of PPAM aid as an advantage. However, in some larger centres, the cost may limit implementing the recommendations fully with 1 PPAM Aid per patient.

Redhead[12,13], Dickstein[15], Hebenton et al.,[16] and Davie-Smith[17] noted its impact on reducing oedema, shaping the residual limb, facilitating venous return, promoting wound healing, decreasing pain, providing psychological boosts, preparing the residual limb for prosthetic socket, and preventing deterioration of postural reflexes. Dickstein[15] determined that early ambulation using the PPAM aid was important to geriatric populations for both the physical and mental benefits, and avoidance of prolonged wheelchair dependence. In this study with 33 patients, 93% were ambulatory within the first week of physiotherapy, relieving pressuring on the remaining limb and preventing unnecessary loading of the cardiovascular system, and 83% went on to be fitted with a prosthesis.

Section II: Timing and Prescription of PPAM aid

Introduction:

This section examines how the PPAM aid is being used in treatments post-operatively and offers recommendations for the best practice to ensure the rehabilitation is specific, measurable and aligned to training principles for prescription and timing.

Recommendations/Findings:

- Aim to commence PPAM aid use on day 7 post-operative; and always within 10 days post-operatively for unilateral TTA (if wound is satisfactory on assessment)
- PPAM aid can commence on day 7 for TFA if wound is healing well
- PPAM aid can be commenced as early as day 5 post-operatively for trauma patients, or patients of other aetiologies such as malignancies, elective orthopaedics, or amputation due to congenital malformation
- Unilateral PPAM aid can be applied 10 days post-TTA if wound is satisfactory on assessment for Bilateral TTA with their prosthesis on their established side
- PPAM aid can be applied if wound is healing well on inspection after the removal of 1st Plaster of Paris (POP) in TTA
- PPAM aid can be applied as many times as necessary in the course of a single day
- The PPAM aid bag (non weight bearing) can be used at lower pressures to gradually ease pain
- Weight bearing should not be commenced until 40mmHg can be tolerated.
- PPAM aid CANNOT be worn continuously for a period of 2 hours

88% of respondents did not use a second POP in TTA and therefore could not comment on the below statement:

- PPAM aid can be applied with second POP in situ in TTA.

Literature Evidence:

Recent evidence has provided some guidance on the timing of when a PPAM aid can be applied, and the prescription of how often and for how long the intervention can be used. In the previous edition of the guidelines, it did not reach consensus that the use of the PPAM aid increased the rehabilitation process resulting in earlier discharge home. Redhead[12,13] was one of the first to report on the timing of application, suggesting that PPAM aid should be commenced on day six post-operatively for compression therapy, with the bag inflated for periods of 5-10 minutes and then gradually increased. In Redhead[12,13] sample of 85 participants, the average time to start was 17 days due to poor wound healing. Hebenton et al.[18] determined that patients who

started PPAM aid within 10 days of amputation were found to have shorter time to casting and final discharge and similarly Lee et al.[11] found that earlier introduction of PPAM aid related to shorter times to rehabilitation milestones, including casting, delivery, and discharge.

Lein's[19] questionnaire investigated who made the decision of when to apply the PPAM aid, with the respondents reporting that 51.1% physiotherapists decided in conjunction with a surgeon, 40% physiotherapists decided independently, and 8.9% surgeons decided independently.

Participants in Dickstein's[15] study routinely used PPAM aid every day, with time and distance of ambulation varying due to patient's physical ability. Those with transtibial amputations walked intermittently for about an hour each day, while transfemoral and established bilateral transtibial walked approximately 20 minutes daily. Lein[19] concluded that PPAM aid was applied once a day by 54.3% of respondents, with a mean time of 27 minutes. Redhead[12,13] suggested that the PPAM aid can be worn continuously for a period of up to 2 hours and can be applied as many times throughout a single day, although twice per day is the usual course of rehabilitation.

Vanross et al.[20] utilized 3-6 weeks of PPAM aid use in the study, with inpatient rehabilitation receiving daily sessions until discharge and outpatient receiving 2 sessions per week. Hebenton et al.[16] assessment of different models of care, found intensive gym sessions, including the use of PPAM aid, and a frequency of 5 days per week to be essential part of the rehabilitation post transtibial amputation.

Ortho Europe instructs that pending a satisfactory wound assessment by a surgeon, the PPAM aid can be applied from 5 day post-operatively.

Due to the lack of evidence, the following recommendations regarding the timing and prescription of PPAM aid use are based on the consensus of 70% or more from the Delphi questionnaire.

Evidence Based Clinical Guidelines for the Use of the Pneumatic Post-Amputation Mobility Aid (PPAM Aid) in Persons with Lower Limb Amputations

Section III: Persons who can use the PPAM aid

Introduction:

This section examines the recommendations for PPAM aid use for persons of amputations with different levels, including transtibial, transfemoral, and knee disarticulation and as well as, unilateral, new bilateral, and existing bilateral amputation.

Recommendations/Findings:

- Application of one PPAM aid and one prosthesis is an acceptable combination for gait re-education
- The PPAM aid is the preferred EWA for those with a TTA who are suitable for limb fitting and the Femurett is preferred for those with a TFA
- PPAM aid should be used along with transfemoral predictor for TFA to help with decision for limb fitting if a femurett is not available
- Application of one PPAM aid and one other EWA (e.g. Femurett) is an acceptable combination for gait re-education

Literature Evidence:

From the literature search, only 3 studies addressed the use of PPAM aid beyond patients with unilateral transtibial amputation. Dickstein's[15] study had 26 below knee participants, 4 above knee participants, and 3 bilateral below knee participants (who were previously ambulatory on one prosthesis). Dickstein[15] reported that both transfemoral and bilateral transtibial groups required closer supervision but were able to complete the study and mobilise on the PPAM aid without negative effects.

Lein's[19] questionnaire reported that the PPAM aid was suitable for transtibial, knee disarticulation, and long transfemoral amputations and additionally found that 23.9% of respondents would use two PPAM aids on a new bilateral amputation. It does not clarify how the treatments were carried out or patient outcomes.

Redhead[12,13] stated that the PPAM aid was suitable for patients of widely differing builds, including those who hard undergone transtibial, transfemoral, knee disarticulation, and existing bilateral amputations.

Ortho Europe is the sole manufacturer of the PPAM aid and identifies it as a partial weight bearing device, indicating two PPAM aids should not be used simultaneously for a new bilateral amputee. Ortho Europe also advertises lengths of 650mm, 750mm, and 850mm length frames. Frames that are larger in girth are available, with corresponding pneumatic and cushion bags.

Section IV: Precautions and Things to monitor

Introduction:

This section considers the safety of patients and items that should be checked or monitor to ensure that the use of the PPAM aid is not harmful or detrimental to the patient.

Recommendations/Findings:

- Use of the PPAM aid requires thorough staff training
- Patients need to give consent and be motivated to use the PPAM aid
- Patients should have cognitive awareness before using the PPAM aid
- Pain should be well controlled when using the PPAM aid
- Patients with a TFA should be able to transfer safely from chair to plinth before the first application of the PPAM aid
- Avoid application of the PPAM aid on bare skin
- The wound should be checked before and after PPAM aid use and throughout the ongoing rehab to make sure there is no infection, deterioration, or ischaemia and to ensure wound is intact when applying the PPAM aid
- PPAM aid can be used on unhealed wounds
- PPAM aid can be used over a skin graft (if it has been cleared by the surgeon)
- Caution needs to be taken when using the PPAM aid with patients who may have significant peripheral neuropathy
- Caution needs to be taken when using the PPAM aid if there is an active wound infection
- Caution needs to be taken when using the PPAM aid if the patient is experiencing phantom pain
- Physiotherapists should be mindful of any reported pain at the time of PPAM aid application and after PPAM aid use prior to progressing with rehabilitation
- Wound healing influences decision to progress to walking aids along with patient safety and cognition
- Risk assessment should always be carried out prior to progression out with parallel bars/or progression of walking aids
- PPAM aid can be used with joint contractures, but the physiotherapist must exercise caution to avoid pressure from the frame
- PPAM aid should be used for one patient at a time if possible. and cleaned between patients

Literature Evidence:

There are a wide variety of precautions and considerations to take into account when using the PPAM aid, which is reflecting in the variation of safety protocols across the literature.

Lein's[19] questionnaire reported that 91.3% of respondents checked the wound at each application. The wound, pain levels, patient ability, and cooperation were all relevant to the decision to use the PPAM aid. Lein[19] discussed the possibility of cross infection as the results of the questionnaires revealed that only 26.1% of respondents cleaned the PPAM aid between patients and 13% did not know if there was a cleaning routine in their department.

Redhead[12,13] indicated the PPAM aid is intended for use by the patient only under the supervision of trained staff. In instances of a fall within the study, Redhead[12,13] found the PPAM aid can be act a barrier of protection for the wound.

Dickstein's[15] safety protocols addressed the wound, identifying that physiotherapists should take note of skin irritation, pain, and reopening of wounds and stating that PPAM aid can be donned over a bandage or open uninfected wound. In line with the manufacturer's guidance, Dickstein[15] indicated weight bearing was limited to 25-50% of body weight.

Vanross et al. [20] investigated the impact of mobilisation with PPAM aid on unhealed wounds, which were defined as wounds greater than 1cm by 1 cm at least 3 weeks post-operatively on dysvascular transtibial amputations and residual limbs with exposed bone were not cause for exclusion from the trial. Prior to mobilisation, wounds were irrigated and cleaned, and necrotic tissue was excised (larval therapy was successfully used in instances of deep, inaccessible necrotic tissue). Dressings chosen for the wound were based on the stage of healing, volume of exudate, and condition of surrounding skin. Participants were warned of increased exudate after mobilisation. If necessary, dressings were changed before and after physiotherapy. Vanross et al.[20] mobilised participants with a PPAM aid for 3 to 6 weeks and found that transcutaneous oxygen levels improved and 74% achieved complete wound healing.

Ham[21] identified that sustained pressures in excess of 25mmHg are potentially harmful, while pressures above 15mmHg reduce total limb flow with a reduction of 50% occurring at a pressure of 40mm Hg. Ham[21] suggested that all pressures should be documented so that possible negative effects are prevented.

In monitoring of electrocardiograms (ECG), Bailey[22] found that PPAM aid use for gait training is within normal limits of exercise stress, but walking outside parallel bars and hopping resulted in greater ECG deviations. Bailey's[22] findings recommended that warm up routines should be part of the exercise session to reduce abnormal cardiac responses and monitoring of ECG changes can help avoid serious cardiac events.

In addition to patient well-being, the equipment should be checked for faults prior to use. The footbed of the frame is prone to wear in the rubber attachment, the frame should be checked

for cracks or rust, and the pneumatic bag should be checked for leaks. The manufacturer suggests the pressure gauge and foot pump be regularly checked if used frequently, this should be carried out by the physiotherapist to ensure pressure accuracy; in addition the local medical physics department should perform regular checks to ensure calibration is accurate.

Local hospital, health board, or trust policy and guidelines will dictate the protocol for infection control. According to the previous PPAM aid guidelines, the PPAM aid bag are to be used for one patient at a time if possible.

Prior to use of a PPAM aid, the physiotherapist should carry out a full assessment of the patient to gain a comprehensive understanding of the present condition, medical history, cognitive state, previous physical ability, pain, sensation, wound healing, range of movement, and strength. The documentation of PPAM aid intervention should include the patient's response during and after use, method of application, pressure over inflation, time spent mobilising, and walking aid used. Additionally, assessment should include analysis of the gait with the PPAM aid. The contralateral limb should also be assessed and monitored in those using the PPAM aid.

Due to the limited evidence, the follow recommendations are based upon the consensus to expand upon the safety precautions.

Section V: Applying the PPAM Aid

Introduction:

This section addresses the procedures and considerations for the initial application of PPAM aid.

Recommendations/Findings:

- PPAM aid use and the introduction of the PPAM aid, should be decided by the physiotherapist and physiotherapy team
- Patients should have the ability to independently sit to stand (STS) in the parallel bars before the first application of the PPAM aid
- PPAM aid should ideally be used within the parallel bars for the initial use
- The PPAM aid can be donned in whatever position is appropriate for the environment and patient e.g. sitting with stump on stump board or in standing
- The size of the PPAM aid should be correct for both height and thigh diameter
- Bariatric PPAM aids should be accessible and appropriately used for bariatric patients
- A calibrated manometer should always be used for application to check for correct pressures
- The patient must be able to tolerate maximum pressure of 40mmHG when standing and non-weight bearing
- The small cushion bag should be inflated with a small amount of pressure and placed distally in the larger bag as cushion
- PPAM aid does not need to be deflated when the patient is resting this is dependent on patient's tolerance
- The PPAM aid bag (non-weight bearing) can continued to be used for compression and reducing oedema for any level of amputation
- When using the PPAM aid with a bilateral TTA (1 PPAM Aid & 1 Prosthesis), the patient should always be within the parallel bars

Literature Evidence:

The manufacturer's guidance instructs that the initial application begin with the pneumatic bag applied for 5 minute trial period at a pressure lower than 40mm Hg. The bag should be removed, the wound should be inspected for adverse reactions before continuing with increased inflation pressure until 40 mm Hg can be reached.

Redhead[12,13] reported the smaller, inner cushion bag should be inflated and invaginated to become padding at the distal end of the residual limb. The manufacturer does not provide instruction on the patient position during application, only indicating the outer pneumatic bag is slid over the leg until in contact with the patient's groin, but Redhead[12,13] suggested to apply the PPAM aid to the patient in sitting between parallel bars with the residual limb extended. A frame that is of suitable girth and length is slid over the outer bag with the top ring of the frame reaching approximately 8 cm below the outer bag. Ensure the rocker foot is in a desirable

position, with the frame being about 2 to 3 cm longer than the contralateral limb as shortening will occur on weight bearing.

While the frame is supported, the outer bag is inflated to a maximum of 40 mm Hg for walking using a calibrated manometer. Ham[21] reported that the newest model of PPAM aid was redesigned so there would be no risk of pressure injury and the accuracy of inflation pressure was solved with an electric pump with automatic cut off at 55mm Hg. The patient can stand to check the length of the PPAM aid, but the bag may need to be deflated to make adjustments.

Dickstein[15] specified that application could be done by physiotherapist, physiotherapist aide, or a family member for transtibial patients, but Lein's[19] questionnaire indicated there was wide variation among physiotherapists in the way PPAM aid is applied, with some being aware of manufacturing instructions and dangers associated with use. 54.3% of respondents claimed to have access to two lengths of frames and 43.5% had 3 frame lengths available. Transfemoral and transtibial bags were available to 69.6% of respondents and 93.5% had access to an inner bag. Less than half used the appropriate bag or the inner bag. 15.2% used a pump without a pressure gauge and 86.5% recommended a level of 40mm Hg. The findings reported that 23.9% of respondents applied the PPAM aid directly to the skin.

Section VI: Progression

Introduction:

This section considers the different walking aids, tasks, and activities for progression with use of a PPAM aid.

Recommendations/Findings:

- Patient can progress out with parallel bars with PPAM aid once independently mobile within bars
- Once independently mobile in parallel bars, progress gait onto walking frame
- PPAM aid can be used with walking frame or elbow crutches
- If mobilising with PPAM aid with a TTA, aim to refer to prosthetist within 14 days post-operatively for limb fitting assessment
- PPAM aid should be used to maintain oedema reduction and optimise fit until delivery of the prosthesis
- PPAM aid should be progressed in terms of time worn, walking distance covered, walking aid used, and task completed.
- Patients should use the same PPAM aid for the entirety of their rehabilitation journey; however, a transition from extra wide to usual width may be needed if their residuum reduces in size
- When appropriate, patients should be progressed on different challenges e.g. obstacle course, different floor surfaces, backward walking, side stepping

Literature Evidence:

The literature search returned three studies that provided insight into previous methods of progression. Dickstein[15] began all participants within the parallel bars, before proceeding to gait training with a walking frame for both transtibial, transfemoral, and bilateral participants. The findings demonstrated that transtibial participants were quicker to progress than transfemoral or bilateral participants, as they required more time in parallel bars and increased supervision while using the walking frames. Lein[19] indicated that a walking frame or two crutches were the minimum walking aid required for a patient mobilising with a PPAM aid. Vierling[23] employed the use of a rollator frame, two crutches, and one cane while mobilising with the PPAM aid. No adverse effects were noted in these instances, but it was indicated that the PPAM aid can limit gait initiation and termination due to the rocker foot.

In the previous guidelines, no consensus was established on the use of PPAM aid on slopes or stairs, so these guidelines aimed to gain a deeper understanding on the progression on the PPAM aid. Vierling[23] investigated the use of the PPAM aid with obstacles, similar to the height of

a stair, and found that although the PPAM aid can limit the ability due to lack of knee flexion, no limitations were noted when using a permanent prosthesis.

It is of note that Dickstein's[15] findings highlighted the importance of general treatments for muscle strengthening and range of motion in conjunction with the progression of a PPAM aid gait training programme.

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Appendix A

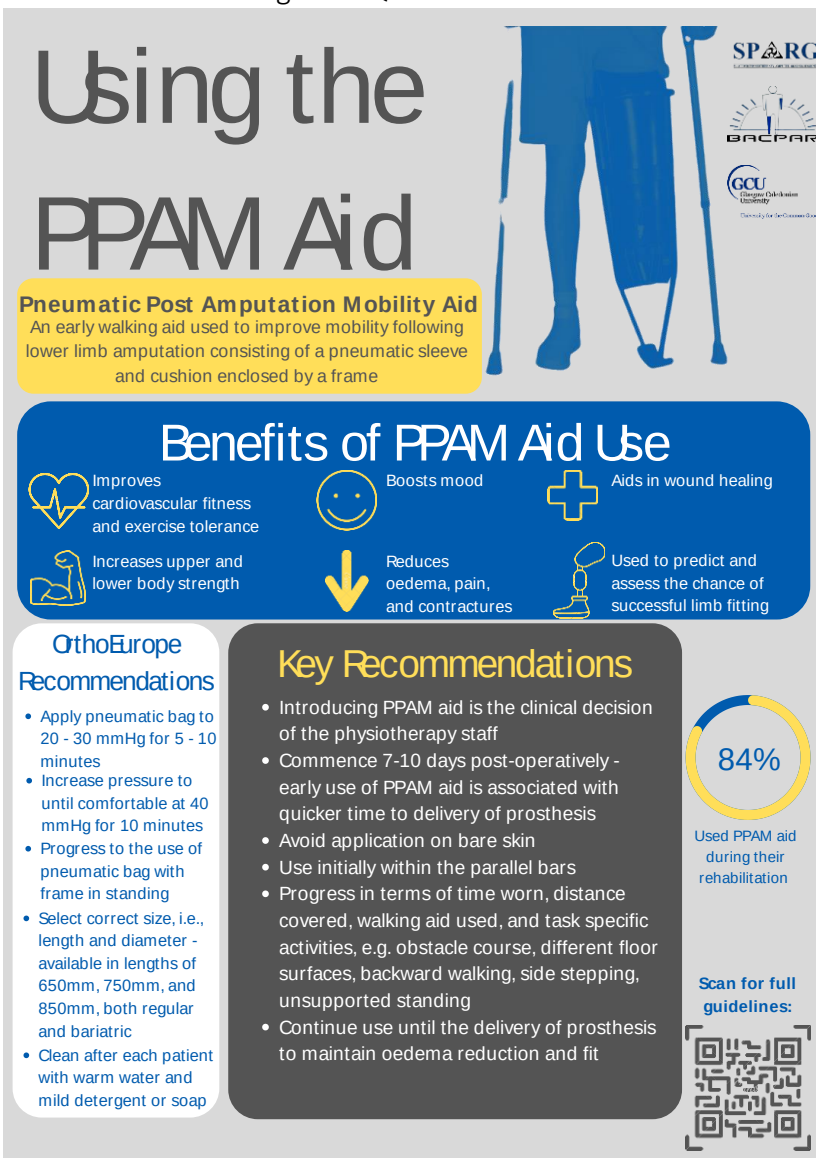
Non-Consensus Results

Surgeon preference may influence when PPAM aid use is commenced.	62%
The PPAM aid can be applied over a shrinker.	46%
If extra padding is used to protect the equipment, the PPAM aid can be used over wounds that still have the clips in, if the patient is comfortable.	66%
The PPAM aid can be used over PICO dressings but not over VAC. (54% of participants felt they did not have enough experience to comment)	30%
Bilateral amputees can use two PPAM aids simultaneously. For clarification: only after patient assessment as dependent on patient ability, fitness level, and wound healing	60%
If staffing is poor, patients using the PPAM aid should be kept within the parallel bars, even if patient is safe when mobilising.	46%
Once confident mobilising out with the parallel bars (e.g. with walking frame around gym/ward), progress to assessment on stairs and uneven surfaces.	48%
If an appropriate candidate for a prosthetic limb, referral for limb fitting should be made only after mobilising with the PPAM aid or other early walking aid	42%
Sanitizing/antibacterial wipes are an appropriate method of cleaning the PPAM aid between patient	66%
Actichlor should be used to clean the PPAM aid between patients.	32%

Appendix B

Guidelines Poster

For display in physiotherapy gym and departments or distribution for patients. Full guidelines can be accessible through the QR code.



Appendix 1: External, patient and peer reviewers

Peer Reviewers who completed the AGREE II tool:

Peer Reviewer	Employing NHS Trust/ Organisation	Clinical Speciality	Job Title
Susan Geddes	University Hospital Ayr	Amputee Rehabilitation Service	Senior Physiotherapist
Louise Tisdale	Royal Wolverhampton Hospitals NHS Trust	Amputee Rehabilitation Service	Clinical Specialist Physiotherapist

Appendix 2: Domains of the Appraisal of Guidelines for Research and Evaluation Instrument (AGREE II)

This international, validated tool is designed to assess the overall quality of a Guideline. The tool contains 23 items and is split into six theoretical quality domains

Domain	Definition
Scope and Purpose	Clarity is needed about the overall objectives of the guidelines being developed and the potential impact on society and patient populations. There should be a clear description of the patient population to which the guidelines are applicable
Stakeholder Involvement	Description of all of the authors' involvement needed (including those just used for consultation or expert advice). A range of authors from differing professional backgrounds is thought to be essential to control potential biases. Stakeholders should have appropriate clinical skills and/or experience and/or technical expertise to justify their involvement in the formulation +/- implementation of the Guidelines (patients views should be included in this process). Target user are unambiguously identified and the guidelines piloted amongst this group.
Rigour of Development	Systematic review and rigorous appraisal of the available evidence should be demonstrated. The methods used for formulating the recommendations are clearly described. External review of the guidelines has been undertaken by appropriate group(s) of individuals.
Clarity and Presentation	Recommendations should be clear and unambiguous. Key recommendations are easy to identify and support material for

	application is included (i.e., – patient information, quick reference guide, etc …)
Applicability	Potential organisational barriers to implementation of the guidelines have been discussed with cost implications identified. Guidelines also suggest audit criteria so that their use and effects on clinical practice may be measured by the Practitioner.
Editorial Independence	Is there independence from the Editorial group from any Funding committee and declaration of any conflicts of interest?

AGREE II Scoring system:

Each of the AGREE II items and the two global rating items are rated on a 7-point scale (1– strongly disagree to 7– strongly agree).

A quality score is calculated for each of the six AGREE II domains. The six domain scores are independent and should not be aggregated into a single quality score.

Domain scores are calculated by summing up all the scores of the individual items in a domain and by scaling the total as a percentage of the maximum possible score for that domain.

The scaled domain score will be:
Obtained score – Minimum possible score ÷ Maximum possible score – Minimum possible score

(Maximum possible score = 7 (strongly agree) x No of items in domain x No of appraisers

Minimum possible score = 1 (strongly disagree) x No of items in domain x No of appraisers)

Each domain was scored using the scoring tool (Appendix 2):-
(Obtained score − Minimum possible score) ÷ (Maximum possible score − Minimum possible score)
The percentage allocated to each of the six quality domains help to form the overall quality rating of the guideline

Appendix 3: Impact of comments from the peer reviewers using the AGREE II tool upon the 2023 Guidelines update process

Domain (Items)	Title	Calculation	Percentage
1 (1-3)	Scope and purpose	(40-6)/(42-6)= 34/36	94.4%
2 (4-6)	Stakeholder involvement	(35-6)/(42-6)=29/36	80.55%
3 (7-14)	Rigour of development	(106-8)/(112-8)=90/104	86.5%
4 (15-17)	Clarity of presentation	(38-6)/(42-6)=32/34	94.12%
5 (18-21)	Applicability	(45-8)/(56-8)=37/48	77.08%
6 (22-23)	Editorial independence	(26-4)/(28-4)=22/24	91.67%

Related AGREE II question/domain	Comments received	Action taken by GUG
General comments	The 1st edition of the clinical guidelines for the Use of the PPAM aid were not readily available, should a note be made of this in terms of improving dissemination / access etc.	The 1st edition of the clinical guidelines were available in paper format only and costed a small fee. This has now been noted at the start of the guideline.
	Do we need to say something about alternative formats for dissemination in view of Equality Disability Inclusivity (EDI) work being carried out?	These guidelines are only available in electronic written format as alternative formats require additional funding which is not available at this time; however SPARG will review this for future versions which are in line with EDI.
Domain 1		
Question 1	It states a quality and consistent Physiotherapy management that is standardized across NHS services – should this not be all users of the identified equipment (i.e. not just NHS) – Private practitioners were included in the Delphi and there was outside of the UK input too – so this guideline should be aimed at all users/clinicians involved in its use	The statement has been amended to clarify that Physiotherapy management includes both NHS services and private practices.
Question 2	The Physiotherapy management beyond the use of the PPAM aid is addressed in the Post op guidelines as well	Reference to *the Clinical guidelines for the pre and post-operative physiotherapy management of adults with lower limb amputations* has been added.
Domain 2		
Question 4	The Vascular Society involvement is noted but is not specific – Specialist Vascular Nurses consulted in the development process. Or other nurses who may be involved in the decision making process to PPAM aid or not?	Vascular Society and Specialist Vascular Nurses were invited to review the guidelines prior to their publication; however were unable to contribute in a timely manner. For future reviews of the guidelines this will be taken into consideration and encouraged at an earlier stage to allow for inclusion.
	It is noted that feedback from Physiotherapists in services outside	All SPARG and BACPAR members who were familiar with PPAM Aid

	the UK have been utilized in the Delphi process (NZ) – it is also used in Australia and Portugal – was the NZ person a convenience inclusion?	guidelines were invited for feedback and the response came from New Zealand rather than any other countries outside the UK.
Domain 3		
Question 11	Independent mobility with the PPAM aid is a good predictor of successful limb fitting-is limb fitting the correct terminology here or should this be – prosthetic provision? -	This was raised at a recent SPARG meeting and the membership were unanimous in the use of the term limb-fitting as it is also consistently used in peer reviewed publications.
	Independent is what? It's use should be supervised and with an aid	The term Independent is a patient managing to walk with the PPAM Aid while using walking aids in a supervised rehabilitation environment. This has now been clarified in the guideline.
	Successful is what – PPAM aid gait not necessarily needed for a prosthesis to aid transfers	Successful refers to limb fitting with a prosthesis for gait and not for transfers only.
Question 12	Evidence for it's use in assessment is not explicit.	Agree that there is little peer reviewed published evidence for its use in assessment and rather agreement is experiential. Future work should be focused on this aspect.
Domain 4		
Question 15	Is it possible /acceptable to present the recommendations/finding first? Readers can then review the literature evidence after to minimize confusion in some of the sections – where there is conflict within these discussions.	This has now been changed to improve the reader experience
	The bag can be used at lower pressures to gradually ease pain – considering the following statement – should this say can be used non weight bearing at lower pressures?	This has now been clarified
	Page 18 are we actually saying that 2 PPAM aids can be walked upon but only in the parallel bars?	No, this has been clarified to read 1 PPAM Aid and 1 Prosthesis for a bilateral patient

	Page 15 says transfer ability between chairs .. Page 18 says stand… which is it ? Do you mean ability to stand before walking?	The patient should have the ability to stand before walking.
	Page 19… Zimmer is a trade name for walking frame?	Zimmer has been replaced with walking frame
	If the residuum reduces in size a transition from Extra wide to usual width may be needed	This clarification has now been added.
Question 16	Some reference to preference for Femurett if appropriate for TK or TF patients noted.	This was not explored as more relevant to pre and post-operative guidelines
	Discussion re the cost of the PPAM aid if it is expected that it is 1 set per patient then it may be difficult to implement the recommendations fully	This has now been highlighted.
	As part of the dissemination of the guidelines reference could be made to the manufacturers online instructions re application of the PPAM aid, the user info produced by SPARG – available to download on the BACPAR website .	This information has now been added.
Question 18	It was presented in 2021 at the VS ASM – not at the 2022??	This has been corrected to 2021
Question 20	Cost discussion as per number 18 . Ensuring that the pumps are checked by Medical Engineering .. (equivalent in private practice)	The pumps should be checked by medical physics as per the manufacturer's instructions and local health and safety policies. This has been added.
Question 21	Absence of a self audit tool to monitor own practice and maintain competency once initial training is carried out.. who is responsible for this training?	The specialist Physiotherapist in the rehabilitation unit is responsible for ensuring staff are correctly trained and competent to apply the PPAM aid. Local competencies and training documents may be utilised to document this.
Question 22	The sole provision by Ortho Europe needs to be stated as previously	This has been clarified

	highlighted – as it is referenced as a source?	
Question 23	I did not see a statement re conflict of interest .. should there be one? If yes the score would be a 1 …	Add in a conflict of interest paragraph